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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,742	05/03/2001	Scott E. Boatman	PA-5259-RFB	8028

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,742

Applicant(s)

BOATMAN ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-7,10-13,16-18,26,27 and 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,8,9,14,15,19-25,29-33 and 35 is/are rejected.
- 7) ☐ Claim(s) 28 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election of species (b) in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon review of the claims, the examiner identified claims 6, 16 and 26-27 as also being drawn to a non-elected invention. Claim 6 recites "an anchor" which is not in the embodiment of figure 4 but figures 6-8. Claim 16 recites "an outer catheter shaft and an inner catheter shaft" which is not in the embodiment of figure 4 but figure 9. Claims 26-27 contain the limitation of a balloon which is not part of the elected invention; therefore, these claims have also been withdrawn below.

Claims 2-3, 5-7, 10-13, 16-18, 26-27 and 36-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In both claims, applicant appears to be establishing an alternate expression. This is assumed since before the last group and "or" is recited. However, each claim

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begins with comprising which makes one believe that all limitations following the “comprising” are present in the subject matter. These claims are not in proper Markush form and therefore, the claim is unclear. It is improper to use the term “comprising” instead of “consisting of.” Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931). One acceptable form of alternative expression recites members as being “selected from the group consisting of A, B and C.” See Ex parte Markush, 1925 C.D. 126 (Comm’r Pat. 1925). See MPEP § 2173.05(h).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 8, 9, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaldany (US Pat# 5,222,949). Kaldany discloses a flexible noncollapsible catheter tube with hard and soft regions. The hard and soft regions are made from polyurethane and have different durometers. See 5:46+. The hard regions are formed by exposing those regions to radiation. Regarding claim 14, the catheter shaft length can be divided into an infinite number of catheter shaft segments (first part, second part, transition zone) that can have different durometers but are all unitarily and continuously formed.

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Claims 1, 4, 6, 8, 9, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Cecchi et al (US pat# 6,165,165). Cecchi discloses a catheter shaft that includes a unitarily and continuously formed tubular portion having a continuously varying durometer along the length of the shaft. See 2:46-57. The catheter has an anchor (34). Regarding claims 9 and 14, the catheter shaft length can be divided into an infinite number of catheter shaft segments (first part, second part, transition zone) that will all have slightly different durometers along the overall length of the shaft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-25, 29-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany in view of Zamore (US Pat# 6,596,818). Kaldany meets the claim limitations as described above but fails to include the unitarily and continuously formed portion (formed portion) comprising an irradiated cross-linkable mixture of a polyamide elastomer and at least one additional cross-linking reactant.

Zamore discloses e-beam irradiation conversion of thermoplastic to thermoset polymers. The method teaches using polyurethanes however, also discloses the use of co-polyamide polymers including PEBAX. See 7:23. The cross-linking reactant includes about 3 percent by weight triallyl isocyanurate. See Example 2; 14:22. Possible cross-linking reactants include

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meta-phenylene dimaleimide. See claims. The formed portion comprises an amount of the cross linking reactant sufficient to give the formed portion a strength generally about equal (albeit greater) to that of an irradiated formed portion without a cross-linking reactant. See 14:62-64. Radiation levels are from about 0.5 to 60 megarads. See table 2.

At the time of the invention, it would have been obvious to incorporate the material and irradiation method including cross-linking reactant of Zamore into the invention of Kaldany. Both inventions are analogous in the art and to the instant invention; therefore, a combination is proper. Zamore teaches that both the material that Kaldany discloses (polyurethane) AND co-polyamide polymers are suitable for the irradiation cross-linking which is a process already used on the device by Kaldany. The motivation for the incorporation of co-polyamide polymers and the method of irradiation with the cross-linking reactant would have been in order to enhance the production capability of the device of Kaldany by expanding the manufacturing materials.

Allowable Subject Matter

Claims 28 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW*.
March 6, 2004


BRIAN L. CASLER
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